WYETH AYERST

Individual Safety Report

3182068-6-00-01

MEDWATCH

CAL PRODUCTS REPORTING PROGRAM

Approved by the FDA on 11/10/93

Mfr report # 8-98295-017A

UF/Dist report #

FDA Use Only

A. Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted] In confidence	62 YR 10/22/1935	[X] female [ ] male	lbs or kgs

B. Adverse event or product problem

1. [X] Adverse event and/or [ ] Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- [ ] death (mo/day/yr)
- [ ] life-threatening
- [X] hospitalization - initial or prolonged
- [X] recovered
- [ ] disability
- [ ] congenital anomaly
- [ ] required intervention to prevent permanent impairment/damage
- [ ] other:

3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)
10/15/1998	01/13/1999

5. Describe event or problem

OVERDOSE. Information has been received from a physician regarding a 63-year-old female patient who had been receiving Effexor (venlafaxine) 375 mg daily for approximately 18 months. Concomitant therapy included an unspecified dosage of Lortab (hydrocodone bitartrate/acetaminophen), Ativan (lorazepam) 2 mg tablets and an unspecified dosage of Tylenol (acetaminophen). Medical history included anemia (etiology unknown) treated with erythropoetin factor, and depression. Reporter suspects that the patient is taking about 850 mg more than prescribed dose over a month's time. A 30 day supply lasts about 28 days. The patient was hospitalized on 20-Oct-98 with elevated liver enzymes and ammonia levels. Follow up information was received 11-JAN-1999. The patient was hospitalized with elevated liver function tests and confusion. Effexor therapy was started OCT-1996 and was discontinued 19-OCT-1998. Concomitant therapy also included Darvocet (propoxyphene/acetaminophen) which was prescribed by another physician. The patient was over using the (Cont.)

6. Relevant tests/laboratory data, including dates

DATE	TEST	RESULTS
10/20/98	SGOT	1400
10/20/98	SGPT	1800
10/20/98	Bilirubin	2.2
10/20/98	Ammonia level	53

RECEIVED JAN 19 1999 By

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

History of anemia, etiology unknown, treated with erythropoetin factor, peptic ulcer disease, chronic fatigue, chronic obstructive pulmonary disease, Wolfe Parkinson White syndrome, no known allergies, smoker (1/2 pack daily for 40 years), no alcohol.

DATE SENT TO FDA
01/18/1999

FDA Form 3500A (facsimile)

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 EFFEXOR
#2 DARVOCET (PROPOXYPHENE/ACETAMINOPHEN) TABLETS

2. Dose, frequency & route used
#1 over 375 mg daily ORAL
#2 DOSE UNKNOWN ORAL

3. Therapy dates (if unknown, give duration)
#1 10/00/1996 to 10/19/1998
#2 UNKNOWN to 10/00/1998

4. Diagnosis for use (indication)
#1 MAJOR DEPRESSION
#2 UNKNOWN

5. Event abated after use stopped or dose reduced
#1 [X] yes [ ] no [ ] doesn't apply
#2 [X] yes [ ] no [ ] doesn't apply

6. Lot # (if known)
#1
#2

7. Exp. date (if known)
#1
#2

8. Event reappeared after reintroduction
#1 [ ] yes [ ] no [X] doesn't apply
#2 [ ] yes [ ] no [X] doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)
See following page

G. All manufacturers

1. Contact office - name/address (& MFG site for devices)
WYETH-AYERST LABORATORIES
170 RADNOR CHESTER ROAD
ST. DAVIDS, PA. 19087

KAREL F. BERNADY, PH.D.

2. Phone number (610) 902-3760

3. Report source (check all that apply)
- [ ] foreign
- [ ] study
- [ ] literature
- [ ] consumer
- [X] health professional
- [ ] user facility
- [ ] company representative
- [ ] distributor
- [ ] other:

4. Date received by manufacturer (mo/day/yr) 01/11/1999

5. (A)NDA # 20-151
IND #
PLA #
pre-1938 [ ] yes
OTC product [ ] yes

6. If IND, protocol #

7. Type of report (check all that apply)
- [ ] 5-day
- [X] 15-day
- [ ] 10-day
- [ ] periodic
- [ ] initial
- [X] follow-up # 1

8. Adverse event term(s)
OVERDOSE
LIVER FUNCTION TESTS ABNORMAL
NPN INCREASED
CONFUSION

9. Mfr. report number
8-98295-017A

E. Initial reporter

1. Name, address & phone #
[redacted] D.O.
[redacted] Drive
Suite [redacted]
[redacted]
[redacted]

JAN 20 1999

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
[X] yes [ ] no	Physician	[ ] yes [X] no [ ] unk

TM WYETH AYERST

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Box B.5 - Describe Event or problem (Continuation)

Darvocet, and the physician felt the narcotic was the "most likely offender". Medical history also included peptic ulcer disease, chronic fatigue, chronic obstructive pulmonary disease, Wolff Parkinson White syndrome, no known allergies, smoking (1/2 pack daily for 40 years), and no alcohol intake. All non-essential medications were discontinued, including Effexor, the patient subsequently recovered.

Box C.10 - Concomitant medical products and therapy dates (exclude treatment of event) (Continuation)

ATIVAN (LORAZEPAM) TABLETS 2 mg daily ORAL (UNKNOWN to UNKNOWN)
DARVOCET (PROPXYPHENE/ACETAMINOPHEN) TABLETS DOSE UNKNOWN ORAL (UNKNOWN to UNKNOWN)
LORTAB (HYDROCODONE BITARTRATE AND ACETAMINOPHEN) DOSE UNKNOWN ORAL (UNKNOWN to UNKNOWN)
TYLENOL (ACETAMINOPHEN) occasional use ORAL (UNKNOWN to UNKNOWN)